K092903

APPENDIX A. 510(K) SUMMARY

DEC - 1 2009

510(k) SUMMARY

Submitter	Maquet GmbH & Co. KG
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Contact Person	Annette Jakob, Regulatory Affairs
Date Prepared	July 29, 2009
Device Trade Name	BORA UP 2080, BORA UP 2080 OP, BORA UP 2080 Mounting
Device Common Name	Powered Suction Pump
Device Classification Name	General Surgery
Device Classification	Class II
Summary of substantial equivalence	The intended use, principles of operation, design, physical characteristics, performance and safety of BORA UP 2080, BORA UP 2080 OP, BORA UP 2080 Mounting are substantially equivalent to Vacuson 40 cleared by the Food and Drug Administration under K042943 on Dec 17, 2004.
Device description	The MEDAP BORA is a high performance, low-noise suction pump designed for continuous operation and suitable for high flow/high vacuum. The vacuum for the MEDAP BORA is produced by an electrically driven pump unit. The pump must be operated with an overflow protection device. The overflow protection device with float prevents the unit from oversuction. In the event of a high filling level, the float rises, closes the suction line and prevents liquid from discharging. In addition, the hydrophobic bacterial and viral filter prevents the penetration of particles and liquid into the suction unit. A bacterial filter paper in the exhaust air area guarantees additional safety for patients and operators. The unit is equipped with a hydrophobic bacterial and viral filter to protect the inside of the pump from bacterial contamination. This hydrophobic bacterial and viral filter must be used when treating infectious patients. The vacuum can be set from 0 to -90kPa (0 to -675 mmHg) using a regulation switch and is controlled using a vacuum gauge.

510(k) SUMMARY (continued)

Indications for Use	The Bora UP 2080, BORA UP 2080 OP and BORA UP 2080 MOUNTING are intended as extraction suction units for aspiration and removal of fluids, and infectious material from wounds or tissue either during surgery or at the patient's bedside.
Technological characteristics	The BORA UP 2080, BORA UP 2080 OP, BORA UP 2080 Mounting incorporate similar fundamental scientific technology as its predicate device.
Performance data	The performance data of BORA UP 2080, BORA UP 2080 OP, BORA UP 2080 Mounting are equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Maquet GmbH and Co. KG
% TÜV SÜD America, Inc.
Mr. Stefan Preiss
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

DEC - 1 2009

Re: K092903
Trade/Device Name: BORA UP 2080, BORA UP 2080 OP, BORA UP 2080 MOUNTING
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: November 13, 2009
Received: November 18, 2009

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX E. INDICATIONS FOR USE STATEMENT

510(k) number (if known)	The 510(k) number has not been issued yet.
Device name	BORA UP 2080, BORA UP 2080 OP, BORA UP 2080 MOUNTING
Indications for Use	The Bora UP 2080, BORA UP 2080 OP and BORA UP 2080 MOUNTING are intended as extraction suction units for aspiration and removal of fluids, and infectious material from wounds or tissue either during surgery or at the patient's bedside.

Prescription Use __X__ (21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092903